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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,421	03/12/2004	John Devane	09487.0003-00	6571

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/798,421	DEVANE, JOHN	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-37,39-42 and 44-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-37,39-42 and 44-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's Reply filed September 19, 2006 is acknowledged. Claims 7, 8, 38 and 43 are canceled. Claims 1-6, 9-37, 39-42 and 44-77 remain under consideration.

In the last Office Action claims 38-51 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The objection under 37 CFR 1.75(c) is maintained over claims 39-42 and 44-51 because the claims recite an intended use without reciting a specific chemical or physical property of the formulation of claim 30 from which they depend.

Claim 2 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Subsequent to the insertion of the term "and" before "spastic colon," the rejection of record under 35 U.S.C. 112, second paragraph is withdrawn.

Claims 1-29 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It was asserted the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention with reasonable clarity to one skilled in the art.

Applicant argues evidence is not set forth why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.

The evidence or reasons to support the assertion that Applicant was not in possession of the subject matter recited in the present claims are as follows.

Although not required, the showing of working examples directed to the administration of N-2,2,3-tetramethylbicyclo-[2.1.1]heptan-2-amine, or a pharmaceutically acceptable salt thereof, wherein an outcome is noted, clearly indicates possession of the claimed subject matter.

In Example 1, page 74, support is provided for a single motility disorder, i.e., (diarrhea-predominant) irritable bowel syndrome.

There is no support for minimizing any side effect, such as those relating to heart rate, blurred vision, bladder function or blood pressure.

On pages 82-83 of the specification, in Example 7, no more than a hypothetical situation is presented for subjects diagnosed with increased gastrointestinal motility diagnosed with diarrhea-dominant irritable bowel syndrome.

Applicant states the formulations disclosed in the specification comprising N-2,2,3-tetramethylbicyclo-[2.1.1]heptan-2-amine demonstrate efficacy in improving IBS symptoms and a dissociation of gastrointestinal motility effects from effects on other systems, including blood pressure, heart rate, vision and bladder function. No such conclusions with respect to "minimizing at least one side effect associated with the administration of a conventional formulation of N-2,2,3-tetramethylbicyclo-[2.1.1]heptan-2-amine", as recited in instant claim 5, or "reducing gastrointestinal motility in a subject" caused by any pathological condition are noted.

The skilled artisan in gastroenterology would reasonably require a more detailed description of both disease states characterized by gastrointestinal hypermotility, that are encompassed by the language of claim 1, and of minimization of side effects. The instant specification fails to provide support for reducing gastrointestinal support in subjects suffering from any abnormal increase in gastrointestinal motility. As such, Applicant has not described to one of ordinary skill in the art an embodiment that meets all the limitations thereof.

The broad language of the claims encompasses essentially any bowel motility disorder regardless of the etiology of the disease process. The rejection of record of claims 1-6 and 9-29 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained because sufficient guidance to support predictable operability of the invention to one of ordinary skill in the art is absent.

Claims 1-77 were rejected under 35 U.S.C. 103(a) in the last Office Action as being unpatentable over Shytle et al., WO 00/35280 or Shytle et al., WO 00/35279. It was asserted Shytle teaches the administration of mecamylamine (N-2,2,3-tetramethylbicyclo-[2.1.1]heptan-2-amine), or an optical isomer thereof, in the treatment of gastrointestinal motility disorders. See claim 62, page 29. Transdermal administrations are disclosed in claims 55 and 63. Dosages are disclosed on page 12. The selection of optimal dosage forms, dosages, dosage regimens and an optimal isomer, or the racemic mixture, are parameters well within the purview of those skilled in the art of formulation chemistry through no more than routine experimentation. Multiple drug therapy is conventional practice in the treatment of gastrointestinal disorders.

Testing in a U.S. Pharmacopeia (USP) Type 2 Apparatus under defined physical and chemical conditions is conventional practice to determine the pharmacokinetics of an active agent in a pharmaceutical formulation.

Applicant argues Shytle's teaching is in a different direction and fail to show a peak:trough plasma ratio of less than about 4:1. Applicant urges Shytle's teaching merely suggest any formulation will work.

Applicant has amended independent claims 1, 30 and 65 to require "the modified release formulation produces a peak:trough plasma level of N-2,2,3-tetramethylbicyclo-[2.1.1}heptan-2-amine of less than about 4:1."

The recitation "less than about 4:1" includes zero. Further, a "modified-release formulation" encompasses a transdermal preparation, as well as a rapid, sustained or delayed-release formulations. See page 6, lines 30-31. Shytle's disclosure encompasses all optically active forms of mecamylamine. See the last paragraph on page 2, the second paragraph on page 3 and the last paragraph on page 15. The open language of the present claims allows for the inclusion of additional active compounds, including optical isomers.

Compositions comprising racemic mecamylamine, as well as both of its stereoisomers, are known in the prior art for use in the treatment of gastrointestinal motility disorders. Various dosage forms and dosages ranges, as those presently claimed, are taught by Shytle.

Shytle teaches or suggests all of the limitations presently claimed with a reasonable expectation of success in reducing gastrointestinal motility in a subject

suffering from an abnormal increase in gastrointestinal motility disorders. The rejection of record Claims 1-6, 9-37, 39-42 and 44-77 under 35 U.S.C. 103(a) as being unpatentable over Shytle et al., WO 00/35280 or Shytle et al., WO 00/35279, is maintained for the reasons of record.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

November 28, 2006

Phyllis Spivack
PHYLLIS SPIVACK
PRIMARY EXAMINER